

wherein the predetermined first limit is based on the following formula: predetermined first limit =  $X \cdot C_{LL}$ , where  $X$  is a linear dimension of the blood collection tube and  $C_{LL}$  is a constant based on at least one factor of the blood collection apparatus, and the predetermined second limit is based on the following formula: predetermined second limit =  $X \cdot C_{UL}$ , where  $C_{UL}$  is a constant based on at least one factor of the blood collection apparatus.

Attached as Exhibit A are marked-up copies of amended claims 1, 4, 19, 21 and 30. Please substitute the amended claims for the pending claims with the same number in the application file.

Please cancel claims 12 and 13 without prejudice.

#### **REMARKS**

This application has been reviewed in light of the Office Action dated June 19, 2001. Claims 1-11 and 14-30 are pending in the application. Claims 1-11 and 14-30 are amended in a manner which is believed to overcome the rejections in the Office Action. Support for the amendments can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure which Applicant is believed to be entitled. No new matter or issues are believed to be introduced by the amendments. Claims 12 and 13 have been cancelled without prejudice. Applicant reserves the right to prosecute the subject matter of claims 12 and 13 in further continuation and/or divisional applications.

In the Office Action, the Declaration was objected to as defective. However, pursuant to 37 CFR 1.63(d)(1), "a newly executed oath or declaration is not required...in a continuation or divisional application..." Applicant respectfully submits that no new oath or declaration is required in this continuation application. Reconsideration and withdrawal of the objection is respectfully requested.

In the Office Action, a priority reference to a previously filed co-pending application is required. The specification is amended to include the required priority reference, as evinced by the clean copy above, to be inserted in the specification.

In the Office Action, claims 1-6, 11-14, 16, 18-25 and 27-28 were rejected under 35 U.S.C. §102(b) by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 4,257,886 to Kessler (Kessler '886).

Referring to FIG. 1, Kessler '886 discloses an apparatus for separating blood components which uses a gel-like barrier material 28 loosely disposed near a closed end 16 of a container 12. (col. 2, lines 47-65). Applicant respectfully traverses the rejections.

The Office Action recites that "...furthermore, Kessler teaches that any means used to place the gel in the container adjacent the closed end of the tube is satisfactory so long as a transverse barrier is formed between the separated phase of the blood upon centrifugation of the device (see col. 3, lines 29-37). Defining the limits of gel to be placed in the tube would have been obvious to a person of ordinary skill in the art depending on the volume of blood to be separated." It is respectfully submitted that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *See* M.P.E.P. § 2143.03, p. 2100-100, Rev. 1 Feb. 2000; *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *See* M.P.E.P. § 2143.01, p. 2100-98, Rev. 1 Feb. 2000; *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicant's original claims recite, *inter alia*, a blood collection apparatus having a gel selectively disposed and, alternatively, disposed along a portion of a central inner surface which defines a predetermined first limit and a predetermined second limit. Neither Kessler '886 and/or any of the references cited, alone or in any proper combination, disclose or suggest Applicant's claimed blood collection apparatus and method. There is no teaching and/or motivation in the prior art to provide Applicant's claimed blood collection apparatus and method.

The Kessler '886 disclosure of "any means to place the gel" does not teach, motivate, or suggest to one skilled in the art, Applicant's claimed apparatus and method. Some of the advantages of Applicant's claimed apparatus and method include limited migration of the gel, a stronger mechanical barrier after centrifugation and lower gel quantity requirements.

Although Applicant disagrees with the Examiner's rejections, in an effort to expedite prosecution, claims 1-30 are amended, as shown above and are believed to clearly and patentably distinguish over Kessler '886 and/or any of the references cited, alone or in any proper combination. These amendments are submitted, not necessarily to overcome any rejections and/or objections in the Office Action, but to further clarify Applicant's disclosure as recited in the claims. Applicant believes that the originally submitted claims are patentable over the materials relied upon by the Examiner. Further, these amendments do not raise new issues, but rather focus those issues already raised during prosecution of the application. Applicant reserves the right to present the originally submitted claims in one or more continuation and/or divisional applications.

With regard to independent claim 1, in contrast to Kessler '886, claim 1 recites: "[a] blood collection apparatus comprising: a blood collection tube defining an inner surface and an end; and a gel being selectively disposed along the inner surface relative to the end based on at least one dimension of the blood collection tube and a volume of a blood sample being collected."

Kessler '886 in no way discloses or suggests such a structural configuration. Kessler '886 does not disclose, *inter alia*, a blood collection apparatus including a gel being selectively disposed along an inner surface relative to an end of a blood collection tube based on at least one dimension of the blood collection tube and a volume of a blood sample being collected. Rather, Kessler '886 relates to a container having a gel loosely disposed therein.

Because of the above distinctions, it is respectfully submitted that independent claim 1 patentably distinguishes and is not obvious over Kessler '886. With regard to claims 2 and 3, ultimately depending from independent claim 1, it is respectfully submitted that claims 2 and 3 are patentable and not obvious over Kessler '886 for at least the reasons outlined hereinabove. Reconsideration and withdrawal of the rejections are respectfully requested.

With regard to independent claim 4, in contrast to Kessler '886, claim 4 recites: "[a] blood collection apparatus comprising: a blood collection tube defining a central inner surface and an end; and a gel disposed along a portion of the central inner surface, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of a blood sample being collected."

Kessler '886 in no way discloses or suggests such a structural configuration. Kessler '886 does not disclose, *inter alia*, a blood collection apparatus including a gel disposed along a portion of a central inner surface of a blood collection tube, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of a blood sample being collected.

Because of the above distinctions, it is respectfully submitted that independent claim 4 patentably distinguishes and is not obvious over Kessler '886. With regard to claims 5, 6, 11, 14, 16 and 18, ultimately depending from independent claim 4, it is respectfully submitted that claims 5, 6, 11, 14, 16 and 18 are patentable and not obvious over Kessler '886 for at least the reasons outlined hereinabove. Reconsideration and withdrawal of the rejections are respectfully requested.

With regard to independent claim 19, in contrast to Kessler '886, claim 19 recites: "[a] blood collection apparatus comprising: means for collecting a sample of blood defining a central inner surface; and a gel disposed along a predetermined portion of the central inner surface, the predetermined portion being predetermined based on at least one dimension of the means for collecting a blood sample and a volume of a blood sample being collected."

Kessler '886 in no way discloses or suggests such a structural configuration. Kessler '886 does not disclose, *inter alia*, a blood collection apparatus including a gel disposed along a predetermined portion of a central inner surface of a means for collecting a sample of blood, the predetermined portion being predetermined based on at least one dimension of the means for collecting a blood sample and a volume of a blood sample being collected.

Because of the above distinctions, it is respectfully submitted that independent claim 19 patentably distinguishes and is not obvious over Kessler '886. With regard to claim 20,

depending from independent claim 19, it is respectfully submitted that claim 20 is patentable and not obvious over Kessler '886 for at least the reasons outlined hereinabove. Reconsideration and withdrawal of the rejections are respectfully requested.

With regard to independent claim 21, in contrast to Kessler '886, claim 21 recites: "[a] method for separating a sample of blood into portions including a light serum portion and a heavy cellular portion, the method comprising the steps of: providing a blood collection tube defining a central inner surface and an end; providing a dispensing apparatus configured to dispense gel along a portion of the central inner surface, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of a blood sample being collected; dispensing the gel via the dispensing apparatus along the portion of the central inner surface; providing the sample of blood within the blood collection tube; and manipulating the blood collection tube to separate the light serum portion of the blood sample from the heavy cellular portion of the blood sample."

Kessler '886 in no way discloses or suggests such a method. Kessler '886 does not disclose, *inter alia*, a method for separating a sample of blood into portions including the step of providing a dispensing apparatus configured to dispense gel along a portion of the central inner surface, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of a blood sample being collected.

Because of the above distinctions, it is respectfully submitted that independent claim 21 patentably distinguishes and is not obvious over Kessler '886. With regard to claims 22-25 and 27-28, ultimately depending from independent claim 21, it is respectfully submitted that claims 22-25 and 27-28 are patentable and not obvious over Kessler '886 for at least the reasons outlined hereinabove. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 7-10 and 30 were rejected under 35 U.S.C. §103(a) over Kessler '886 in view of U.S. Patent No. 3,516,385 to Walling (Walling '385). Applicant respectfully traverses this rejection, however, in an effort to expedite prosecution, claims 7-10 and

30 are amended to clearly and patentably distinguish over Kessler '886 in any proper combination with Walling '385, as discussed above.

Kessler '886 has been discussed. Referring to FIGS. 4A and 5, Walling '385 discloses an apparatus for coating the interior of tubular members with a coating material via nozzles 59 having a plurality of holes 76. (col. 7 line 41- col. 9, line 50). Kessler '886 and Walling '385 in no way disclose or suggest a structure as recited in Applicant's amended claim 4, from which claims 7-10 ultimately depend. Walling '385 does not cure the deficiencies of Kessler '886 in that Kessler '886 and Walling '385 do not disclose, *inter alia*, a blood collection apparatus including a gel disposed along a portion of a central inner surface of a blood collection tube, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of a blood sample being collected.

Because of the above distinctions, it is respectfully submitted that claims 7-10, ultimately depending from independent claim 4, patentably distinguish and are not obvious over Kessler '886 in any proper combination with Walling '385. Reconsideration and withdrawal of the rejections are respectfully requested.

With regard to independent claim 30, Kessler '886 and Walling '385 have been discussed. In contrast, claim 30 recites: "[a] blood collection apparatus for separating a sample of blood into portions including a light serum portion and a heavy cellular portion, the blood collection apparatus comprising: a blood collection tube having an open end, a closed end and defining a central inner surface therebetween, at least a portion of the central inner surface having a non-stick coating, the blood collection tube being configured for receipt of a volume of a blood sample; and a dispensing apparatus having a nozzle disposed at a distal end thereof, the nozzle including a plurality of openings disposed about a circumference defined by the nozzle, said plurality of openings configured to dispense gel along a portion of the central inner surface, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the open end; wherein the predetermined first limit is based on the following formula:  $\text{predetermined first limit} = X \cdot C_{IL}$ , where X is a linear dimension of the blood collection tube and  $C_{IL}$  is a constant based on at least one factor of the blood collection apparatus, and the predetermined second limit is based on the following formula: predetermined

second limit =  $X \cdot C_{UL}$ , where  $C_{LL}$  is a constant based on at least one factor of the blood collection apparatus.”

Kessler ‘886 and Walling ‘385 in no way disclose or suggest such a structural configuration. Walling ‘385 does not cure the deficiencies of Kessler ‘886 in that Kessler ‘886 does not disclose, *inter alia*, a blood collection apparatus for separating a sample of blood into portions including a blood collection tube having an open end, and a gel dispensed along a portion of the central inner surface, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the open end, wherein the predetermined first limit is based on the following formula: predetermined first limit =  $X \cdot C_{LL}$ , where  $X$  is a linear dimension of the blood collection tube and  $C_{LL}$  is a constant based on at least one factor of the blood collection apparatus, and the predetermined second limit is based on the following formula: predetermined second limit =  $X \cdot C_{UL}$ , where  $C_{LL}$  is a constant based on at least one factor of the blood collection apparatus.”

Because of the above distinctions, it is respectfully submitted that independent claim 30 patentably distinguishes and is not obvious over Kessler ‘886 with any proper combination with Walling ‘385. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 1-4, 12-14, 16 and 18-20 were rejected under 35 U.S.C. §102(e) by U.S. Patent No. 5,853,600 to McNeal et al. (McNeal ‘600). Applicant respectfully traverses this rejection, however, in an effort to expedite prosecution, claims 1-4, 14, 16 and 13-20 are amended, to clearly and patentably distinguish over McNeal ‘600, as discussed.

Referring to FIGS. 1-6, McNeal ‘600 discloses a blood separation system having a tube 10 with internal ribs 20 and a separation gel 24. (col. 2, line 60 - col. 4, line 46). McNeal ‘600 in no way discloses or suggests a structural configuration as recited in amended claim 1. McNeal ‘600 does not disclose, *inter alia*, a blood collection apparatus including a gel being selectively disposed along an inner surface relative to an end of a blood collection tube based on at least one dimension of the blood collection tube and a volume of a blood sample being collected.

Because of the above distinctions, it is respectfully submitted that independent claim 1 patentably distinguishes and is not obvious over McNeal ‘600. With regard to claims 2 and 3, ultimately depending from independent claim 1, it is respectfully submitted that claims 2 and 3

are patentable and not obvious over McNeal '600 for at least the reasons outlined hereinabove. Reconsideration and withdrawal of the rejections are respectfully requested.

McNeal '600 in no way discloses or suggests a structural configuration as recited in amended claim 4. McNeal '600 does not disclose, *inter alia*, a blood collection apparatus including a gel disposed along a portion of a central inner surface of a blood collection tube, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of a blood sample being collected.

Because of the above distinctions, it is respectfully submitted that independent claim 4 patentably distinguishes and is not obvious over McNeal '600. With regard to claims 14, 16 and 18, ultimately depending from independent claim 4, it is respectfully submitted that claims 14, 16 and 18 are patentable and not obvious over McNeal '600 for at least the reasons outlined hereinabove. Reconsideration and withdrawal of the rejections are respectfully requested.

McNeal '600 in no way discloses or suggests a structural configuration as recited in claim 19. McNeal '600 does not disclose, *inter alia*, a blood collection apparatus including a gel disposed along a predetermined portion of a central inner surface of a means for collecting a sample of blood, the predetermined portion being predetermined based on at least one dimension of the means for collecting a blood sample and a volume of a blood sample being collected.

Because of the above distinctions, it is respectfully submitted that independent claim 19 patentably distinguishes and is not obvious over McNeal '600. With regard to claim 20, ultimately depending from independent claim 19, it is respectfully submitted that claim 20 is patentable and not obvious over McNeal '600 for at least the reasons outlined hereinabove. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 15, 17, 26 and 29 were objected to as being dependent upon a rejected base claim. However, these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant respectfully submits that in view of the above amendments and remarks all claims presently pending in the application are allowable over the art of record.



In view of the foregoing amendments and remarks, it is respectfully submitted that claims 1-11 and 14-30 presently pending in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicant's undersigned attorney.

Please charge any deficiency as well as any other fees which may become due at any time during the pendency of this application, or credit any over payment of such fees to deposit account no. 50-0369. Also, in the event that any extensions of time for responding are required for the pending application, please treat this paper as a petition to extend the time as required and charge deposit account no. 50-0369 therefor.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "P. Sorell".

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Date: October 19, 2001



## EXHIBIT A

1. (Amended) A blood collection apparatus comprising:
  - a blood collection tube defining an inner surface and an end; and
  - a gel being selectively disposed along the inner surface relative to the end based on at least one dimension of the blood collection tube and a volume of a blood sample being collected.
  
4. (Amended) A blood collection apparatus comprising:
  - a blood collection tube defining a central inner surface and an end; and
  - a gel disposed along a portion of the central inner surface, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of a blood sample being collected.
  
19. (Amended) A blood collection apparatus comprising:
  - means for collecting a sample of blood defining a central inner surface; and
  - a gel disposed along a predetermined portion of the central inner surface, the predetermined portion being predetermined based on at least one dimension of the means for collecting a blood sample and a volume of a blood sample being collected.
  
21. (Amended) A method for separating a sample of blood into portions including a light serum portion and a heavy cellular portion, the method comprising the steps of:
  - providing a blood collection tube defining a central inner surface and an end;
  - providing a dispensing apparatus configured to dispense gel along a portion of the central inner surface, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of a blood sample being collected;
  - dispensing the gel via the dispensing apparatus along the portion of the central inner surface;
  - providing [a] the sample of blood within the blood collection tube; and



manipulating the blood collection tube to separate the light serum portion of the blood sample from the heavy cellular portion of the blood sample.

30. (Amended) A blood collection apparatus for separating a sample of blood into portions including a light serum portion and a heavy cellular portion, the blood collection apparatus comprising:

a blood collection tube having an open end, a closed end and defining a central inner surface therebetween, at least a portion of the central inner surface having a non-stick coating, the blood collection tube being configured for receipt of a volume of a blood sample; and

a dispensing apparatus having a nozzle disposed at a distal end thereof, the nozzle including a plurality of openings disposed about a circumference defined by the nozzle, said plurality of openings configured to dispense gel along a portion of the central inner surface, the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the open end;

wherein the predetermined first limit is based on the following formula: predetermined first limit =  $X \cdot C_{LL}$ , where  $X$  is a linear dimension of the blood collection tube and  $C_{LL}$  is a constant based on at least one factor of the blood collection apparatus, and the predetermined second limit is based on the following formula: predetermined second limit =  $X \cdot C_{UL}$ , where  $C_{LL}$  is a constant based on at least one factor of the blood collection apparatus.